Those skilled in the art are in the business of diagnosing and treating people in need of antiandrogens, and the Specification teaches and exemplifies suitable such hosts (e.g. Specification, p.4, lines 9-29; Examples II & III). Androgen-dependent pathologies and antiandrogenic treatments are well-known in the art, as are diagnostic methods for determining whether a patient is in need of such treatments or is subject or predisposed to such pathologies.

Attached is an expert Declaration under 37CFR1.132 averring to the foregoing, and confirming that the Specification reasonably conveys possession of the invention as claimed to those skilled in the art.

35USC112, first paragraph (enablement)

The test for enablement is whether the specification would have enabled one skilled in the art to practice the invention as claimed without undue experimentation.

Claim 1 recites a two-step method for providing an antiandrogen to a host determined to be in need thereof: 1) contacting the host with an effective amount of an antiandrogenic, optionally substituted 3-3'-diindolylmethane (DIM); and 2) detecting a resultant antiandrogenic response in the host (e.g. Specification p. 4, lines 4-6; Claim 1). The Specification plainly enables this two-step method.

The method is applied to a host determined to be in need of an antiandrogen. The Specification teaches that DIM is an antiandrogen, and shows that DIM operates similar to other androgen receptor antagonists like Casodex (e.g. Specification, p.16, line 25 – p.17, line 25). Those skilled in the art are in the business of diagnosing and treating people in need of antiandrogens, and the Specification teaches and exemplifies suitable such hosts (e.g. Specification, p.4, lines 9-29; Examples II & III).

The first step is simply contacting the host with an effective amount of an antiandrogenic, optionally substituted DIM. The Specification teaches and exemplifies how to prepare and administer the subject compositions (e.g. Specification, p.7, line 11 – p.9, line 7; Examples II and III). Effective amounts of the compositions are readily determined empirically (e.g. Specification, p.9, lines 4-7; National Cancer Institute, clinical trial enrollment announcement NCT00305747, "Diindolylmethane in Treating Patients With Nonmetastatic Prostate Cancer...", attached).

The second step is simply detecting a resultant antiandrogenic response in the host. The Specification teaches that DIM is an antiandrogen, and shows that DIM operates similar to other androgen receptor antagonists like Casodex (e.g. Specification, p.16, line 25 – p.17, line 25). Those skilled in the art are in the business of diagnosing and treating people in need of antiandrogens, and the Specification teaches and exemplifies suitable such hosts (e.g. Specification, p.4, lines 9-29; Examples II & III). In addition, the Specification teaches and exemplifies a wide variety of clinically relevant and validated animal models for antiandrogen activity (e.g. Specification, p.5, lines 13-16)

Attached is an expert Declaration under 37CFR1.132 averring to the foregoing, and confirming that one of ordinary skill in the art would be able to practice the claimed invention without undue experimentation.

35USC112, second paragraph

The test for determining whether a claim complies with the definiteness requirement is whether the claim as a whole apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function of the patent claim.

The Action objects to the word "reduction" as used in Claim 3 in the phrase "the resultant antiandrogenic response is a *reduction* in the pathology or progress of the pathology." What constitutes a "reduction" in a pathology or progress of the pathology is self-evident to one skilled in the art. One of ordinary skill in the art would understand the metes and bounds of this phrase.

Attached is a an expert Declaration under 37CFR1.132 averring to the foregoing, and confirming that the claims are sufficiently clear such that one of ordinary skill in the art to which the invention pertains would understand the metes and bounds of the claims and be on notice as to what is the scope of the claims.

35USC103

Claims 1-19 were rejected under 35 U.S.C. 103(a) as being obvious over Firestone et al (U.S. Pat No 6,001,868) in view of Safe (US 20020115708). U.S. Pat. No. 6,001,868 is disqualified as prior art under 35 U.S.C. 103(c) pursuant to the following Statement:

STATEMENT CONCERNING COMMON OWNERSHIP

The subject Application and U.S. Patent No. 6,001,868 were, at the time the invention of the subject Application was made, owned by the Regents of the University of California. Assignments for this Application and U.S. Patent No. 6,001,868 are recorded at Reel/Frame 008888/0081 and 014630/0190, respectively.

Obviousness Type Double Patenting

An obviousness-type double patenting rejection is applicable when claimed subject matter is not patentably distinct from subject matter claimed in a commonly owned patent, and requires a showing that the application claims are obvious over the claims of the cited patent.

Here, the subject claims recite a two-step method for providing an antiandrogen to a host determined to be in need thereof: 1) contacting the host with an effective amount of an antiandrogenic, optionally substituted 3-3'-diindolylmethane (DIM); and 2) detecting a resultant antiandrogenic response in the host. These claims are expressly limited to targeting a host determined to be in need of antiandrogen therapy.

The commonly-owned, cited U.S. Pat. No. 6,001,868 has only three claims:

> 1. A method of inhibiting tumor cell growth comprising contacting a target tumor cell with, or administering to an individual in need thereof, an effective amount of an indole-3-carbinol compound or a derivative thereof, wherein said compound is stable in acidic aqueous solution, said inhibition is estrogen-independent and said compound is not indole-3-carbinol, 3,3'-diindolylmethane or indole carbazole.
>
> 2. A method for evaluating the growth inhibitory activity of an I3C derivative, said method comprising the steps of:
>
> contacting a cell with an effective amount of an I3C derivative;
> measuring the CDK6 expression in said cell; and
> evaluating said activity, wherein the reduction in CDK6 expression is correlated with the growth inhibitory activity of said compound.
>
> 3. The method of claim 2 wherein said growth inhibitory activity is estrogen-independent.

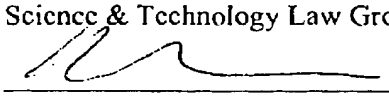
The claims of U.S. Pat. No. 6,001,868 do not teach or suggest the subject claims; they do not teach or suggest that treating with DIM a host determined to be in need of antiandrogen therapy. Accordingly, the present invention, at the time it was made, would not have been

obvious to one of ordinary skill in the art at the time the invention was made over the claims of the cited patent.

Attached is a an expert Declaration under 37CFR1.132 averring to the foregoing, and confirming that the claims at issue would not have been obvious to one of ordinary skill in the art at the time the invention was made over the claims of U.S. Pat. No. 6,001,868

The Examiner is invited to call the undersigned if he would like to amend the claims to clarify the foregoing or seeks further clarification of the claim language. Please charge our Deposit Account No.19-0750 (order B03-074-1) any fees, necessary extensions of time, or credit any overcharges relating to this communication.

Respectfully submitted,
Science & Technology Law Group



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Encl. Declaration under 37CFR1.132
National Cancer Institute, clinical trial enrollment announcement NCT00305747

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